

REMARKS

The pending Office Action addresses and rejects claims 1-6, 11-13, 15, 24, and 37-40. Applicants respectfully request reconsideration in view of the amendments and remarks herein.

Amendments to the Claims

Applicants amend claim 39 to recite that the selectively expandable balloon is detachably connected to the distal portion of the body. Support for this amendment can be found throughout the specification and drawings, for example in Figure 4A and in paragraphs [0045] and [0070]. No new matter is added.

Interview Summary

Applicants thank Examiner Swiger for extending the courtesy of a telephone interview on January 15, 2008 to Applicants' representatives. With respect to the § 102(e) rejection of claims 1, 15, and 37 over the Winkler reference, Applicants' representatives explained that Winkler lacks a support with at least one outlet on a surface thereof, as required by claim 1. The Examiner agreed that Winkler lacks this limitation and to withdraw the rejection. With respect to the § 103(a) rejection of claims 39-40 over the Reiley reference, the Examiner indicated that the amendment made herein to claim 39 is sufficient to overcome the rejection. With respect to the § 103(a) rejections of claims 2-6, 11-13, and 38 over the Winkler and Zdeblick references and the § 103(a) rejection of claim 24 over the Winkler, Zdeblick, and Marchosky references, the Examiner agreed that the deficiencies of Winkler enable independent claims 1 and 24 overcame the rejections.

Claim Rejections Pursuant to 35 U.S.C. § 102(e)

Claims 1, 15, and 37 are rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,695,760 ("Winkler"). Applicants respectfully disagree.

Independent claim 1 recites an intervertebral fusion device that includes a body that has a proximal portion along a major axis and a distal portion along the major axis. The body defines a conduit substantially parallel to the major axis and the conduit extends throughout the body. The device also includes a support at the distal portion that is configured to support vertebrae in a

distracted position while the vertebrae fuse. The support includes a conduit that is in fluid communication with the conduit defined by the body and that has at least one outlet on a surface of the support. The distal portion of the body is configured to selectively engage the support and at least a portion of the body or the support has a height distinct from a width taken along a cross-section of the portion of the body or support perpendicular to the major axis. The portion of the body or the support can distract vertebrae, between which the portion has been placed, by rotation of the body or the support about the major axis.

As agreed by the Examiner during the interview summarized above, Winkler fails to teach or even suggest the device of claim 1 because it lacks a support including a conduit *with at least one outlet on a surface of the support*. The Winkler balloon (46) altogether lacks such an outlet and is thus incapable of forming the claimed support. Instead, the Winkler balloon (46) has a solid, unbroken surface with no outlets whatsoever. *See Winkler* at FIGS. 1, 3, 4B; col. 5, lns. 1-15. This is by necessity, as even a single outlet in the Winkler balloon would allow inflation gas or fluid to escape, making inflation impossible. *See id.*

Accordingly, for at least the reasons described above, claim 1 distinguishes over Winkler and represents allowable subject matter. Claims 15 and 37 are allowable at least because they depend from an allowable base claim.

Claim Rejections Pursuant to 35 U.S.C. § 103(a) – “Reiley”

Claims 39-40 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,066,154 (“Reiley”). Applicants respectfully disagree.

Claim 39 recites an intervertebral fusion device that includes a body having a proximal portion along a major axis of the body and a distal portion along the major axis. The body defines a conduit substantially parallel to the major axis and the conduit extends throughout the body. The device also includes a selectively expandable balloon detachably connected to the distal portion of the body, the selectively expandable balloon being configured to support vertebrae in a distracted position while the vertebrae fuse. An inner volume of the expandable balloon is in fluid communication with the conduit defined by the body and the balloon is formed of a biodegradable polymer.

As agreed by the Examiner during the interview summarized above, Reiley lacks the selectively expandable balloon *detachably connected to the distal portion of a body* required by claim 39. Rather, there is no means for detaching the Reiley balloon (12) from the catheter (21). See *Reiley* at FIG. 1. In addition, since the Reiley device is only intended for transient insertion, no skilled artisan would have been motivated to modify it to include a detachably connected balloon as claimed.

Accordingly, claim 39 is not obvious over Reiley and represents allowable subject matter. Claim 40 is likewise allowable at least because it depends from claim 39.

Claim Rejections Pursuant to 35 U.S.C. § 103(a) – “Winkler and Zdeblick”

Claims 2-6, 11-13, and 38 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Winkler in view of U.S. Patent No. 6,375,655 (“Zdeblick”). Applicants respectfully disagree.

Each of the rejected claims depend ultimately from claim 1 and thus include all the limitations thereof. As explained above, and as agreed by the Examiner during the interview summarized herein, Winkler is deficient with respect to claim 1 because it lacks the claimed support. Since Zdeblick is equally deficient, the cited references fail to render any of claims 2-6, 11-13, or 38 obvious and these claims represent allowable subject matter.

Claim Rejections Pursuant to 35 U.S.C. § 103(a) – “Winkler, Zdeblick, and Marchosky”

Claim 24 is rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Winkler in view of Zdeblick and further in view of U.S. Patent No. 6,413,278 (“Marchosky”). Applicants respectfully disagree.

Claim 24 recites a kit for providing a fusion-promoting material that includes an intervertebral fusion device and a flowable material. The intervertebral fusion device includes a body that defines a conduit that extends throughout the body. The distal portion of the body is configured to selectively engage a support and the support defines a conduit in fluid communication with the conduit defined by the body. The conduit has at least one outlet on a surface of the support.

For the same reasons discussed above with respect to claim 1, and as agreed by the Examiner during the above-summarized interview, Winkler lacks the support required by claim 24. Since both Zdeblick and Marchosky fail to remedy this deficiency in Winkler, claim 24 is not obvious and represents allowable subject matter.

Conclusion

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicants' amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

Date: January 16, 2009

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